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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,847	12/08/2000	Liang C. Dong	ARC 2644 R1	2029

7590 04/05/2005

Samuel E Webb
Alza Corporation
c/o Johnson & Johnson
One Johnson & Johnson Plaza WH3321
New Brunswick, NJ 08933

EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,847	DONG ET AL.	
	Examiner	Art Unit	
	Retford-Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 53-72 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 53-72 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

Acknowledgement: The Amendment filed 6/28/04 is acknowledged.

Status of Claims

1. Claims 1-52 are cancelled in view of applicant's amendment.

2. Claims 53-72 are newly added and pending.

Withdrawal of Claim Rejections:

Because applicant cancelled claims 1-52, the rejection of claims 1, 3, and 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention is moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 52-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudnic et al (US 5, 952,004) in view of Eckenhoff et al (US 4, 692, 326).

The claims are drawn toward sustained release oral dosage formulation of antiviral drug, lubricant and osmogent wherein the drug is present in a solvent consisting of surfactant (non-ionic) ant wherein the drug and solvent are present in specified amounts (wt/%). The dosage formulation further comprises a wall defining a compartment, the wall comprising a semi-permeable layer, an expandable layer located within the compartment and in fluid communication with the permeable layer. The drug formulation is in the form of a gelatin capsule and a barrier layer is located within the capsule between the drug composition and the expandable layer.

Rudnick et al (Patent '004) discloses stable, drug delivery systems for poorly soluble active agents including HIV protease inhibitors, surfactant (col 6, lin 1-5). The formulations are administered in capsules such as controlled release soft gelatin capsules or tablet (col 7, lin20-55).

Patent '004 does not teach how the capsules are configured to release the formulation over the controlled period of time and whether there is bilayer located within the drug and expandible layer.

Eckenhoff et al (Patent '326) discloses controlled release oral capsules semipermeable wall for delivery of beneficial agent (col 4, lin 50-60 and col 6, lin 1-8). The capsule is configured with osmogent and polymer material that is water swellable (col 10, lin 15-55) and col 11, lin 5-25). According to Eckenhoff et al, the capsule has inner layer and plug (gelatin) that are polymeric, contains osmagent and has ability to maintain the stability of drug agent contained therein during storage and during delivery of the agent (col 10, lin 15-55, col 11, lin 5-30 and col 14, lin 15-20). Furthermore, the capsule has expandable, swellable plug in the mouth of the capsule (figure 8) while the body portion of the capsule also comprises expandable, swellable portion in parallel arrangement with the thermosensitive agent containing composition; this is relied upon by the examiner as an expandable barrier layer (figure 9 at col 4, lin 15-30).

One of ordinary skill would have been motivated to combine the disclosures in the prior art cited to make a drug delivery device for delivery of antiviral agents. One of or ordinary skill would expect that by adjusting the amounts and types of fluid imbibing and retaining polymers, one of ordinary skill would to achieve the instant dosage form configuration with the motivation of providing controlled release of the formulation as was achieved in Patent '326 (col 5, lin 40-65, continuing to col 6, lin 1-8).

Response to Arguments

Applicant's remarks filed April 16, 2003 have been considered but are not persuasive.

Applicant argues that claim 53 recites a sustained release oral dosage form that can incremse patient's sustained compliance, thereby minimizing the potential of drug resistance, that nelfinavir, a protease inhibitor, could be solubilized in a surfactant by up to 60 wt%. The antiviral drug composition recited in claim 53 is also substantially free of in-situ drug aggregation and provides substantially improved drug bioavailability.

In response, the drug nelfinavir is not claimed and emulsions described in Rudnic are permitted as reading on the claims because of the scope of the instant claims.

Applicant argues that the formulations disclosed in Rudnic et al. are emulsions unlike the drug formulation claimed in the invention (claim 53), contending that unlike the disclosure in the prior art, the instant claims are drawn toward liquid antiviral drug composition that is homogeneous drug solution that does not include water.

In response, a homogeneous solution is not claimed and the scope of the claims permits a dispersion of drug particles in an emulsion.

Applicant argues that Patent '326 does not teach a barrier layer between the antiviral drug composition and the expandable layer in the capsule and therefore the formulation in the prior art is distinguished from the instant claims (specifically, claims 66, or as recited in claim 68).

In response, as discussed, the body portion of the capsule also comprises expandable, swellable portion in parallel arrangement with the thermosensitive agent containing composition--this is relied upon by the examiner as the expandable barrier layer (figure 9 at col 4, lin 15-30) in so far as applicant has provided no evidence for the criticality of the barrier layer for the efficient and successful delivery of the drug in the capsule.

Conclusion: No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Respectfully,

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

RoB

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600